UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

Z.H. by and through KEVIN HUTCHENS and CHRISTIN HUTCHENS, individually, and as parents and next friends of Z.H.	)	**CASE NO.1:14CV176**
Plaintiffs,	)	**JUDGE CHRISTOPHER A. BOYKO**
Vs.	)	
ABBOTT LABORATORIES, INC. and ABBVIE, INC.	)	**ORDER**
Defendant.	)	

CHRISTOPHER A. BOYKO, J:

This matter is before the Court on Defendants' Motion in Limine to Exclude References to Off-Label Marketing or Promotion (ECF # 105) and Defendants' Motion to Exclude References to Scientific and Medical Data Relating to Injuries other Than Those Alleged by Plaintiffs and Post-Dating the Minor Plaintiff's June 2003 Birth. (ECF # 100). For the following reasons, the Court grants, in part, Defendants' Motion on off-label use and denies Defendants' Motion on post-birth data.

Motions in Limine

"Motions in Limine are generally used to ensure evenhanded and expeditious management of trials by eliminating evidence that is clearly inadmissible for any purpose." *Indiana Insurance Co. v. General Electric Co.*, 326 F.Supp. 2d 844, 846 (N.D.Ohio 2004) (citing

Jonasson v. Lutheran Child and Family Serv., 115 F.3d 436, 440 (7th Cir.1997)). A "motion *in limine*, if granted, is a tentative, interlocutory, precautionary ruling by the trial court reflecting its anticipatory treatment of the evidentiary issue . . . the trial court is certainly at liberty '* * * to consider the admissibility of the disputed evidence in its actual context.'" *State v. Grubb*, 28 Ohio St.3d 199, 201-202 (1986) (citing *State v. White*, 6 Ohio App.3d 1, 4 (1982)). "Indeed, even if nothing unexpected happens at trial, the district judge is free, in the exercise of sound judicial discretion, to alter a previous in limine ruling." *Luce v. United States*, 469 U.S. 38, 41 (1984).

The Sixth Circuit has instructed that the "better practice" is to address questions regarding the admissibility of broad categories of evidence "as they arise." *Sperberg v. Goodyear Tire & Rubber Co.*, 519 R.2d 708, 712 (6th Cir. 1975). "[A] court is almost always better situated during the actual trial to assess the value and utility of evidence." *Owner-Operator Independent Drivers Ass'n v. Comerica Bank*, No. 05-CV-0056, 2011 WL 4625359, at *1 (S.D.Ohio Oct.3, 2011). It is noteworthy that denial of a motion in limine does not necessarily mean that the evidence, which is the subject of the motion, will be admissible at trial. *Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F.Supp. 2d 844, 846 (N.D.Ohio 2004).

Fed.R.Evid. 401 defines relevant evidence as evidence tending to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence. Moreover, Fed.R.Evid. 402 provides that evidence that "is not relevant is not admissible."

Off-Label Marketing and Promotion

Defendants seek to exclude any argument, testimony and evidence regarding Defendants'

alleged off-label promotional/marketing activities and materials. Christin Hutchens was prescribed Depakote by Dr. Foldvary to treat her for an FDA approved on label use; to control her seizures. There is no evidence any off-label promotional or marketing materials affected her decision to prescribe Depakote to Christin. Defendants contend that any testimony concerning its off-label marketing and promotion of Depakote is irrelevant and could simply confuse the jury. Its prejudicial impact greatly outweighs any relevance and should therefore, be excluded under Fed. R. Evid. 401 and 403.

In opposing Defendants' Motion, Plaintiffs argue that Defendants' off-label marketing and promotion of Depakote is relevant to show Defendants' disregard for the safety of the public, thus, it is relevant to Plaintiffs' punitive damages claim.

The Court agrees with Defendants that any testimony regarding Defendants' marketing and promotion of Depakote for off-label uses is irrelevant and, even if relevant, its prejudicial value outweighs its probative value. Christin Hutchens was not prescribed Depakote for an off-label use therefore, any such testimony is irrelevant to Plaintiffs' failure to warn claim. The Court has already allowed Plaintiffs to proffer evidence and testimony regarding marketing and promotion of Depakote as an AED.

Therefore, the Court excludes any evidence or testimony on Depakote' promotion and marketing of Depakote for off-label uses for Plaintiffs' case-in-chief. The Court may revisit the issue of promotion and marketing of Depakote for off label use as it relates to Plaintiffs' punitive damage claim, however, the only information to be considered will be materials and promotions prior to Z.H.'s birth.

Injuries other than those suffered by Plaintiffs

Defendants move the Court to exclude post-birth AED risk data about injuries other than those suffered by Z.H. Defendants argue any such evidence is irrelevant to causation in this case because it has no bearing on the actual harm suffered by Plaintiffs for which they seek to recover.

Plaintiffs oppose the Motion contending that post birth AED risk data is relevant to causation because it relates directly to Defendants ongoing duty to study and warn of all Depakote risks. Post-birth risk data is relevant to what Defendants knew or should have known about the risks of Depakote and both the Illinois and Southern District of Ohio courts that have held Depakote trials have determined the information is relevant. Plaintiffs allege that because Depakote's formulation has not changed since it was introduced, Plaintiffs' expert may rely on such evidence to opine on what Defendants should have known at the time of Z.H.'s birth. Comparative studies would be essential to Dr. Foldvary's prescribing decision even if the label had warned of injuries not suffered by Z.H.

Judge Dlott in the *Rheinfranck* case allowed post-birth risk data to be proffered holding:

> [S]cientific and medical data issued after [the minor plaintiff's] 2004 birth may be relevant and probative of data that could have and should have been known before [the minor plaintiff] was conceived. This evidence is also relevant to the issue of causation, because it is undisputed that Depakote's formulation has not changed since it was marketed in 1983. As such, Plaintiffs will be allowed to introduce medical and scientific evidence, with proper foundation, if that evidence can be linked to the causation issues in the case.

The Court agrees with Judge Dlott that post-birth data may be relevant to causation as it relates to what Defendants should have known about the risks of birth defects from Depakote use on women of child bearing age. Plaintiffs may offer such evidence, provided that Plaintiffs

demonstrate by expert testimony, to a reasonable degree of expert certainty, that the post-birth data on birth defects and comparatively increased teratogenicity of Depakote should have been known by Defendants prior to Z.H.'s birth.

IT IS SO ORDERED.

s/ Christopher A. Boyko
CHRISTOPHER A. BOYKO
United States District Judge

Dated: January 10, 2017